PATENT ABSTRACTS OF JAPAN

(11)Publication number : 2003-102849
(43)Date of publication of application : 08.04.2003

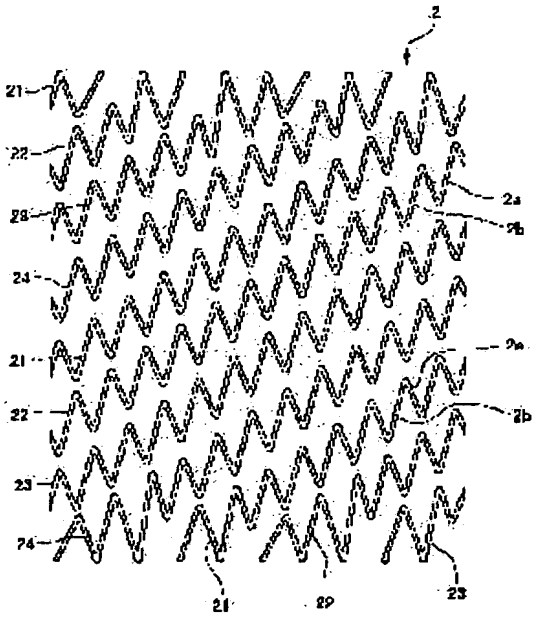
(51)Int.Cl. A61M 29/02
A61L 31/00

(21)Application number : 2001-302399
(22)Date of filing : 28.09.2001

(71)Applicant : TERUMO CORP
(72)Inventor : TAKAHASHI MAKOTO
IWAMI JUN

(54) STENT INDWELLING IN LIVING BODY

(57)Abstract:
PROBLEM TO BE SOLVED: To provide a stent indwelling in a living body having sufficient flexibility, reduced in the number of change points as a whole and well curved after indwelling.
SOLUTION: The stent 1 indwelling in the living boy is formed into an almost cylindrical shape using a wire material and compressed at the time of insertion into the living body to be reduced in its diameter and restored to the shape before contraction at the time of indwelling in the living body. This stent 1 is equipped with a stent body 2 having such a form that a plurality of linear spiral elements 21, 22, 23, and 24 molded into a spiral shape using the wire-like material having a zigzag structure are arranged in parallel to the axial direction of the stent 1 without connecting the linear spiral elements 21, 22, 23, and 24 and a cylindrical cover 3 for holding the stent body 2 to the arranged state of a plurality of the linear spiral elements and closing the side surface of the stent body 2.



LEGAL STATUS

[Date of request for examination]

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

[Date of final disposal for application]

[Patent number]

[Date of registration]

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's

decision of rejection]
[Date of extinction of right]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

CLAIMS

[Claim(s)]
[Claim 1] It is the stent for detention in the living body which is formed in the shape of a cylindrical shape with the body, is compressed at the time of living body interpolation close, reduces the diameter of, and is restored to the configuration before contraction at the time of detention in the living body. a line -- this stent the line of a zigzag structure -- two or more lines spirally fabricated with the body -- a spiral object -- the stent -- shaft orientations -- almost -- parallel -- and each line -- with the stent body used as the gestalt arranged without a spiral object connecting this stent body -- said two or more lines -- the stent for detention in the living body characterized by having tubed covering which blockades the side face of said stent body while holding the arrangement condition of a spiral object.
[Claim 2] said stent body -- three or more lines -- the stent [according to claim 1] for detention in the living body currently formed with the spiral object.
[Claim 3] said two or more lines -- the stent [according to claim 1 or 2] for detention in the living body which is that in which the spiral object is carrying out regular-intervals alienation mostly, respectively.
[Claim 4] said line -- the stent [according to claim 1 to 3] for detention in the living body from which the part located in the both ends of said stent body of a spiral object serves as the location where the shaft orientations of said stent body have the same all mostly.
[Claim 5] said line -- the stent [according to claim 1 to 4] for detention in the living body to which, as for the free end located in the both ends of said stent body of a spiral object, width of face consists approximate circle-like of other parts widely.
[Claim 6] said line -- the stent [according to claim 1 to 4] for detention in the living body from which, as for the part located in the both ends of said stent body of a spiral object, all serve as a flection or a bend mostly.
[Claim 7] said line -- the stent [according to claim 1 to 4] for detention in the living body from which, as for the part located in the both ends of said stent body of a spiral object, all serve as a bend.
[Claim 8] Said some of stent bodies [at least] are the stent [according to claim 1 to 7] for detention in the living body exposed from said tubed covering.
[Claim 9] Said tubed covering is stent [according to claim 1 to 8] for detention in the living body which is that by which some ingredients which are formed of the porosity film and the glue line and form a glue line are flowing in the pore of said porosity film.
[Claim 10] said line -- the stent [according to claim 1 to 10] for detention in the living body in which the spiral object is formed with the superelastic metal.
[Claim 11] Said stent body is stent [according to claim 10] for detention in the living body currently formed by processing one superelastic metallic pipe.
[Claim 12] The inside side film with which said tubed covering was prepared in said stent body inside, It consists of an external surface side film prepared in the external surface side of said stent body. At least one side of this inside side film and this external surface side film serves as a tube-like object. Furthermore, stent [according to claim 1 to 11] for detention in the living body which pinched said stent body between this inside side film and this external surface side

film, and has fixed through side-face opening of a stent body.

[Translation done.]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] This invention relates to the stent for detention in the living body used for the improvement of the narrow segment produced in the living body, such as an organ of a blood vessel, a bile duct, a trachea, an esophagus, an urethra, and others.
[0002]
[Description of the Prior Art] Various stent is proposed, in order to insert in the narrow segment of living body lumina, such as an organ of a blood vessel, a bile duct, an esophagus, a trachea, an urethra, and others, or a coelome and to secure a lumen or coelome space conventionally. The stent is distinguished by the self expander bull stent and the balun expander bull stent by the function and the detention approach. In order for there to be no extension in the stent itself and to detain the stent in the purpose part, after inserting the stent in the purpose part, the balun expander bull stent locates balun in the stent, makes balun extend, makes the stent expand according to the extended force of balun (plastic deformation), is stuck to the inside of the purpose part, and is fixed. Therefore, in this type of stent, expansion of the above stent is needed.
[0003] On the other hand, as for the self expander bull stent, the stent itself has contraction and extension. After inserting in the purpose part where the stent is shrunk in order to detain the stent in the purpose part, the stress which carried out the load for maintenance of a contraction condition is removed. For example, after shrinking the stent, containing and making the tip of this tube reach to the purpose part in the tube of an outer diameter smaller than the bore of the purpose part, it is carried out by extruding the stent from a tube. By being released from a tube, a stress load is canceled, and the extruded stent is restored and extended to the configuration before contraction. Thereby, it is stuck and fixed to the inside of the living body organ (for example, blood vessel) of the purpose part. In this type of stent, the expansion like the balun expander bull stent is unnecessary, and it is easy the technique.
[0004]
[Problem(s) to be Solved by the Invention] Various things are proposed as such self expander bull stent. There is blood vessel stent specifically shown in JP,4-32662,B. Although many straight-line parts are connected and being formed in the closed loop of a zigzag structure, this stent has the problem that the whole stent becomes upright, when a straight-line part is lengthened, in order to use it for a long narrow segment. Moreover, when the above-mentioned stent was detained in two or more body cavity, the coelome might explode by too much extended holding power, the detention activity was still more difficult, and the stent might deviate from the narrow segment. Then, the purpose of this invention is equipped with sufficient flexibility, and as the whole stent, there are few changing points and they are for the curve after detention to offer the good stent for detention in the living body.
[0005]
[Means for Solving the Problem] What attains the above-mentioned purpose is as follows.
(1) It is the stent for detention in the living body which is formed in the shape of a cylindrical shape with the body, is compressed at the time of living body interpolation close, reduces the

diameter of, and is restored to the configuration before contraction at the time of detention in the living body. a line -- this stent the line of a zigzag structure -- two or more lines spirally fabricated with the body -- a spiral object -- the stent -- shaft orientations -- almost -- parallel -- and each line -- with the stent body used as the gestalt arranged without a spiral object connecting this stent body -- said two or more lines -- the stent for detention in the living body equipped with tubed covering which blockades the side face of said stent body while holding the arrangement condition of a spiral object.

[0006] (2) said stent body -- three or more lines -- the stent for detention of the above (1) currently formed with the spiral object in the living body.

(3) said two or more lines -- the above (1) which is that in which the spiral object is carrying out regular-intervals alienation mostly, respectively, or the stent for detention of (2) in the living body.

(4) said line -- the above (1) from which the part located in the both ends of said stent body of a spiral object serves as the location where the shaft orientations of said stent body have the same all mostly thru/or one stent for detention in the living body of (3).

(5) said line -- the above (1) from which, as for the free end located in the both ends of said stent body of a spiral object, width of face consists approximate circle-like of other parts widely thru/or one stent for detention in the living body of (4).

(6) said line -- the above (1) from which, as for the part located in the both ends of said stent body of a spiral object, all serve as a flection or a bend mostly thru/or one stent for detention in the living body of (4).

(7) said line -- the above (1) from which, as for the part located in the both ends of said stent body of a spiral object, all serve as a bend thru/or one stent for detention in the living body of (4).

[0007] (8) Said some of stent bodies [at least] are the above (1) exposed from said tubed covering thru/or one stent for detention in the living body of (7).

(9) Said tubed covering is the above (1) which is that by which some ingredients which are formed of the porosity film and the glue line and form a glue line are flowing in the pore of said porosity film thru/or one stent for detention in the living body of (8).

(10) said line -- the above (1) in which the spiral object is formed with the superelastic metal thru/or one stent for detention in the living body of (10).

(11) Said stent body is the stent for detention of the above (10) currently formed by processing one superelastic metallic pipe in the living body.

(12) The inside side film with which said tubed covering was prepared in said stent body inside, It consists of an external surface side film prepared in the external surface side of said stent body. At least one side of this inside side film and this external surface side film serves as a tube-like object. Furthermore, the above (1) which pinched said stent body between this inside side film and this external surface side film, and has fixed through side-face opening of a stent body thru/or one stent for detention in the living body of (11).

[0008]

[Embodiment of the Invention] The stent of this invention is explained using the example shown in the drawing. Drawing 1 is the perspective view of one example of the stent for detention of this invention in the living body, and drawing 2 is the development view of the stent body of the stent shown in drawing 1 . the stent 1 for detention of this example in the living body -- a line -- it is the stent for detention in the living body which is formed in the shape of a cylindrical shape with the body, is compressed at the time of living body interpolation close, reduces the diameter of, and is restored to the configuration before contraction at the time of detention in the living body. And the stent of this invention the line of a zigzag structure -- two or more lines spirally fabricated with the body -- the spiral objects 21, 22, 23, and 24 -- the shaft orientations of the stent -- almost -- parallel -- and each line -- with the stent body 2 used as the gestalt arranged without the spiral objects 21, 22, 23, and 24 connecting the stent body 2 -- two or more lines -- while holding the arrangement condition of the spiral objects 21, 22, 23, and 24, it has the tubed covering 3 which blockades the side face of the stent body 2.

[0009] The stent 1 of this example consists of a stent body 2 and tubed covering 3. As shown in

drawing 1 , the encapsulation (blockade) of the side attachment wall (a peripheral face, inner skin or a peripheral face, and inner skin) of the stent body 2 is carried out with the tubed covering 3. For this reason, it prevents that a body tissue invades in the stent 1 from the exterior of the stent 1. Although the stent 1 of this example is variously considered by the path of the coelome to detain, it is a tube-like object, and 2.0-30mm, an outer diameter is 2.5mm - 20mm, a bore is a 1.6-19.1mm thing preferably 1.0-29mm, and die length is 10-110mm preferably 5-200mm. In addition, in this example, as stent 1, it is compressed at the time of living body interpolation close, the diameter is reduced, and it explains using the example applied to the so-called self expander bull stent which a stress load is canceled at the time of detention in the living body, and is restored to the configuration before contraction. two or more lines of the shape of the zigzag structure to which the stent body 2 used for the stent 1 of this example has opening on the side face of a cylindrical pipe configuration, and a spiral -- the spiral objects 21, 22, 23, and 24 serve as a gestalt located in a line almost in parallel. each line -- the diameter of the spiral objects 21, 22, 23, and 24 can be expanded by being a zigzag structure at the time of restoration, and the curved narrow segment can also curve along with it by being a spiral-like.

[0010] four lines arranged in juxtaposition as the stent body 2 of this example is shown in drawing 2 which developed the stent body 2 in the stent 1 of drawing 1 -- it is formed with the spiral objects 21, 22, 23, and 24. thus, a spiral configuration -- two or more lines -- by forming with the spiral objects 21, 22, 23, and 24 shows to drawing 3 -- as -- the shaft orientations of the stent 1, and a line -- the include angle alpha which the direction of a spiral of a spiral object makes shows drawing 4 -- as -- a spiral configuration -- one line -- it can be made smaller than the include angle beta at the time of forming with a spiral object, and the stent 1 can be made more flexible. the line arranged in juxtaposition -- as for a spiral object, it is desirable that it is three or more. the line especially arranged in juxtaposition -- as for a spiral object, 3-5 are desirable. the stent of this example -- four lines -- it is formed with the spiral object. four lines which form the stent body 2 of this example -- it connects [in / no / a part] but the spiral objects 21, 22, 23, and 24 are in the condition that each became independent.

[0011] The stent body 2 of this example has a zigzag structure by considering as the shape of a continuous typeface of "<", as shown in drawing 2 . furthermore, the above -- "-- forming the shape of a typeface of <" with short line part 2a (about 2.0-16.1mm) from which die length differs, and long line part 2b (about 2.5-43.6mm) -- one line -- it is formed so that the spiral objects 21, 22, 23, and 24 may serve as a spiral configuration as a whole. moreover, a line -- the pitch between flections of a spiral object (if it puts in another way one line distance between top-most vertices of the flection in a spiral object) has 2.0-8.0 desirablemm. moreover, a line -- the include angle (interior angle) of the flection in a spiral object has desirable 25-45 degrees. and one line -- in a spiral object, although all the pitches between flections, i.e., the include angle of a flection, (interior angle) may be the same, they may differ partially. for example, the line of a part located in the center section of the stent 1 -- the line of the part to which the pitch between flections of a spiral object is located in both ends -- it is good also as a thing shorter than the pitch between flections of a spiral object. the line of a part which similarly is located in the center section of the stent 1 -- the line of the part to which the include angle (interior angle) of the flection of a spiral object is located in both ends -- it is good also as a thing smaller than the include angle (interior angle) of the flection of a spiral object. By doing in this way, the extended force of a center section can be made higher than both ends as stent 1. moreover, one line -- although the pitch of a spiral object may also be the same in the whole, you may differ partially. for example, the line of a part located in the center section of the stent 1 -- the line of the part to which the pitch of a spiral object is located in both ends -- it is good also as a thing shorter than the pitch of a spiral object. thus, also by carrying out, the extended force of a center section can be made higher than both ends as stent 1.

[0012] furthermore, two or more lines [stent / 1 / of this example] as a whole -- the spiral object has carried out regular-intervals alienation mostly, respectively. that is, the stent 1 -- as a whole -- all lines -- in a spiral object, the spiral pitch is the same. however, it restricts to such a thing -- not having -- a line -- the spiral pitches of a spiral object may differ partially. for example, the line of a part located in the center section of the stent 1 -- the line of the part to

which the spiral pitch of the spiral object itself is located in both ends -- it is good also as a thing shorter than the pitch of a spiral object. By doing in this way, the extended force of a center section can be made higher than both ends as stent 1. furthermore, the stent 1 -- the line of a part located in the center section of the stent 1 as a whole -- the line of the part to which the pitch between flections of a spiral object is located in both ends -- it is good also as a thing shorter than the pitch between flections of a spiral object. the line of a part which similarly is located in the center section of the stent 1 -- the line of the part to which the include angle (interior angle) of the flection of a spiral object is located in both ends -- it is good also as a thing smaller than the include angle (interior angle) of the flection of a spiral object. thus, also by carrying out, the extended force of a center section can be made higher than both ends as stent 1. furthermore, two or more lines -- if the spiral objects 21, 22, 23, and 24 are formed almost in parallel -- **** -- ****ing -- each line -- although the pitch in a spiral object or the include angle (interior angle) of a flection may be the same, they may differ.

[0013] and -- the stent 1 of this example -- a line -- the part located in the both ends of the stent body 2 of the spiral objects 21, 22, 23, and 24 serves as the location where the shaft orientations of the stent body 2 have the same all mostly. the line located in the both ends of the stent body 2 if it explains using drawing 2 -- the line located in the part of the spiral objects 21, 22, 23, and 24, i.e., the both ends of the stent body 2, -- the flection and the free end of the spiral objects 21, 22, 23, and 24 are in the condition of having been extended so that it might arrive at the both ends of the stent body 2. By doing in this way, the extended force of both ends can be made high as stent 1. furthermore, the line located in the both ends of the stent body 2 in the stent 1 of this example -- in the free end of the spiral objects 21, 22, 23, and 24, width of face has become large approximate circle-like from other parts. By doing in this way, the amount of free edge can make into few things effect which it has on a detention part wall.

[0014] furthermore, the stent 50 shown in drawing 5 and drawing 6 R> 6 as stent -- like -- the both ends of the stent body 52 -- a line -- the free end of the spiral objects 21, 22, 23, and 24 forms -- not having -- a line -- as for the part located in the both ends of the stent body of the spiral objects 21, 22, 23, and 24, all may serve as a flection. thus, the line located near the both ends of the stent body 52 by carrying out -- as for all of the free end of the spiral objects 21, 22, 23, and 24, some is located in a central site from both ends. the stent of this example -- a line -- the both ends of the spiral objects 21, 22, 23, and 24 serve as a flection instead of the free end. By doing in this way, the extended force of both ends can be made high as stent 50, and effect which the amount of free edge has on a detention part wall can be further made into fewer things.

[0015] furthermore, the line located in the both ends of the stent body 62 like the stent 60 shown in drawing 7 and drawing 8 R> 8 as stent -- the flection of the spiral objects 21, 22, 23, and 24 may be a bend. By doing in this way, the extended force of both ends can be made high as stent 60, and effect which the amount of free edge has on a detention part wall can be further made into fewer things. furthermore, like the stent 70 shown in drawing 9 and drawing 10 R> 0 as stent the both ends of the stent body 72 -- a line -- the free end of the spiral objects 21, 22, 23, and 24 forms -- not having -- a line -- the part located in the both ends of the stent body of the spiral objects 21, 22, 23, and 24 the line further located in the both ends of the stent body 72 by all serving as a flection -- the flection of the spiral objects 21, 22, 23, and 24 may be a bend. thus, the line located near the both ends of the stent body 72 by carrying out -- as for all of the free end of the spiral objects 21, 22, 23, and 24, some is located in a central site from both ends. the stent of this example -- a line -- the both ends of the spiral objects 21, 22, 23, and 24 serve as a bend instead of the free end. By doing in this way, the extended force of both ends can be made high as stent 70, and effect which the amount of free edge has on a detention part wall can be further made into fewer things.

[0016] Synthetic resin or a metal is used as an ingredient of the stent body 2. A thing with a degree of hardness and elasticity is used to some extent, and biocompatibility resin of synthetic resin is desirable. Specifically, there are polyolefine, polyester, a fluororesin, etc. As polyolefine, polyethylene and polypropylene are mentioned, for example and PTFE, ETFE, etc. are mentioned, for example as polyethylene terephthalate, polybutylene terephthalate, and a fluororesin as

polyester. Moreover, as a metal, stainless steel, a tantalum, titanium, a nickel titanium alloy, and an elastic metal can be used. Especially, an elastic metal is desirable.
[0017] As an elastic metal, a superelastic alloy is desirable. Generally a superelastic alloy is called shape memory alloy, and shows superelastic at living body temperature (near 37 degree C) at least. It is the Ti Ni alloy of 49 - 53 atom %nickel especially preferably. The Cu-Zn alloy of 38.5 - 41.5-% of the weight Zn, the Cu-Zn-X alloy of 1 - 10-% of the weight X (X=Be) The nickel-aluminum alloy of 36 - 38 atom %aluminum, such as Si, Sn, aluminum, and Ga, etc., Moreover, the thing to consider as the Ti-nickel-X alloys (X=Co, Fe, Mn, Cr, V, aluminum, Nb, W, B, etc.) which permuted some alloys of Ti-nickel by X 0.01 to 10.0%, Or a mechanical property is changeable timely by choosing the conditions of cooling working ratio or/and the last heat treatment by considering as the Ti-nickel-X alloy (X=Cu, Pb, Zr) which permuted a part of Ti Ni alloy by 0.01 - 30.0% of atom. A mechanical property is changeable timely by furthermore choosing the rate of cold working, and/or a final treatment using a Ti-nickel-X alloy.
[0018] Shaping of the stent body 2 can be performed by removing the part which serves as the free passage section from laser beam machining (for example, YAG laser), an electron discharge method, chemical etching, cutting, etc. for example, in an elastic metallic pipe. and the buckling strength (yield stress at the time of a load) of the superelastic alloy used -- 5-200kg/mm2 (22 degrees C) -- more -- desirable -- 8-150kg/mm2 and restoration stress (yield stress at the time of unloading) -- 3-180kg/mm2 (22 degrees C) -- 5-130kg /is [mm] 2 more preferably. Even if it makes superelastic [here] deform to the field which the usual metal deforms plastically in service temperature (bending, tension, compression), it means recovering in the original configuration mostly, without needing heating after release of deformation.
[0019] Furthermore, as for the stent body 2, it is desirable to be formed by processing a superelastic metallic pipe. concrete -- the stent body 2 of this example -- the line from a superelastic metallic pipe -- it is producible by removing except the part used as a spiral body (stent body 2). thereby -- each -- a line -- it really in which the changed part of physical properties rapid as a whole of a spiral body is not formed becomes a formation object. When there is a rapid changed part of physical properties, the deformation moving state in which the part differed from other parts is shown. And there is a danger of metal stress starting the part from which physical properties differed, and damaging from the part. Moreover, if the changed part of physical properties exists, as stent, it becomes unnatural, and deformation will form flow unnatural in the style of [which flows the interior] blood, and will cause restenosis.
[0020] In addition, the superelastic metallic pipe used for formation of the stent body 2 It dissolves in inert gas or a vacuum ambient atmosphere, the ingot of superelastic alloys, such as a Ti Ni alloy, is formed, and this ingot is ground mechanically. By then, hot pressing and extrusion By forming a large diameter pipe and repeating a dice drawing process and a heat treatment process successively after that, it can narrow-diameter-ize to predetermined thickness and the pipe of an outer diameter, and, finally a front face can be manufactured chemical or by carrying out physical polish. Laser beam machining (for example, YAG laser), an electron discharge method, chemical etching, cutting, etc. can perform processing of a superelastic metallic pipe, and those concomitant use may perform further. Thus, when the time (at the time [At the time / If it puts in another way / of detention] of stress unloading) (condition whose diameter was reduced) of the escape of the stent and un-detaining [of the stent] is compared, the stent body 2 produced by processing a superelastic metallic pipe is extent prolonged a little in the shaft orientations of the stent at the time of un-detaining [of the stent], and there are few differences of the configuration between both and differences of a dimension. For this reason, there is little deformation at the time of configuration restoration in the living body, that is, there is almost no motion of the edge of the stent in the living body [at the time of configuration restoration]. Therefore, it is rare to do damage to a living body wall at the time of configuration restoration. Furthermore, as for the external surface of the stent, it is desirable to consider as the condition of there being no edge and having beveled in the whole. Thereby, a stent body can prevent more certainly doing damage to a living body wall and the tubed covering 3.
[0021] The whole stent body 2 is covered in the stent 1 of this example by the tubed covering 3. The tubed covering 3 in the stent 1 consists of an inside side film 14 prepared in the inside of

the stent body 2 as shown in drawing 1 and drawing 11 , and an external surface side film 15 prepared in the external surface side of the stent body 2, and the inside flank film 14 and the external surface side film 15 serve as a tube-like object. The tubed covering 3 is equipped with the inside film 14 and the outside film 15 which cover jointly the stent body 2 including the side attachment wall which carries out opening in the stent 1 of this example. Furthermore, the tubed covering 3 is equipped with the glue lines 14a and 15a (14a and 15a may be these quality of the materials.) which exist between a film 14, between films 15 and films 14 and 15, and the stent body 2. Furthermore, as shown in drawing 5 , while pinching the stent body 2 by between the inside side film 14 and the external surface side film 15, the films 14 and 15 of two sheets have fixed by glue lines 14a and 15a. Since the tubed covering 3 is formed so that the stent body 2 may be pinched, it does not have balking from the stent body 2 of the tubed covering 3, and prevents separation with the stent body 2 after the time of the detention activity of the stent 1, and detention, and the tubed covering 3.

[0022] Thus, since the tubed covering 3 is formed so that the stent body 2 may be pinched, its deformation flattery nature of the tubed covering 3 to deformation of the stent body 2 is high, and it is rare for the tubed covering 3 to serve as a failure of deformation of the stent body 2. Furthermore, since the fixing parts of the inside film 14 and the outside film 15 are distributing to the whole stent 1, this thing cannot be found to a part strongly [stress] at the time of use and detention, and there is also little danger of fracture of the tubed covering 3 in a fixing part. That in which it is used, and it has plasticity or elasticity and that in which films 14 and 15 have glue lines 14a and 15a and an adhesive property has a certain amount of reinforcement is used. For example, a fluororesin film, a polyolefine film, polyester, thermoplastic polyurethane, a polyvinyl chloride, an ethylene-vinylacetate copolymer, a polyamide elastomer, silicone rubber, etc. can be used. As a fluororesin film, PTFE, ETFE, etc. can be used, as a polyolefine film, polyethylene, polypropylene, etc. can be used and polyethylene terephthalate, polybutylene terephthalate, etc. can be used as polyester, for example. A 10-200-micrometer thing is [that what is necessary is just a 5-300-micrometer thing] suitable for the thickness of a film more preferably.

[0023] Furthermore, it is suitable for films 14 and 15 that it is the porous membrane formed with the above synthetic resin. Since glue line formation resin flows in the pore in a film by using porous membrane, glue lines 14a and 15a and fixing reinforcement can become high, and a film 14 and a film 15 can prevent the exfoliation at the time of use, and can grasp the stent body 2 firmly. As a porosity film, that whose void content is about 25 - 80% is suitable. Moreover, an about 0.1-10-micrometer thing is suitable for a narrow diameter hole. If it is the range of the above-mentioned void content, there is also little invasion in the living body, and it is satisfactory also to the physical properties of the tubed covering 3. As a porosity film, what was formed by the extending method, the solid-liquid-separation method, the beam irradiating method, etc. can be used. What was preferably formed by the strong high extending method, especially the strong biaxial extending method is suitable.

[0024] As glue lines 14a and 15a, as long as it has an adhesive property on films 14 and 15, what kind of thing may be used. Moreover, when films 14 and 15 have plasticity and elasticity, that in which the glue line also has elasticity and plasticity is desirable. It is possible to use, if it is resin meltable to the solvent which has a glue line as an example of glue lines 14a and 15a, and it is the quality of the material which can stop the gestalt of a film even if a film is dissolved to some extent in a solvent with films 14 and 15 by the solvent into the insoluble quality of the material or adhesion time amount (inside of the time amount which has transpired the solvent from the glue line). Under the present circumstances, as for the glue line which will be dissolved if films 14 and 15 are porosity, invading into pore is desirable.

[0025] Specifically as a glue line, meltable fluororesin etc. is in THF (tetra-hydroxy furan) at meltable polyurethane and DMF (dimethyl formaldehyde). Temporary immobilization of the stent body 2 can be carried out, a glue line solvent can be applied to the periphery of a film 14, a film 15 can be arranged on the periphery, and it can paste up by transpiring a solvent. Moreover, as tubed covering 3, glue lines 14a and 15a may be formed with thermoplastics, and what has the melting point higher than glue line formation resin may be used for films 14 and 15. As thermoplastics which forms glue lines 14a and 15a, a thermoplastic fluororesin, polyolefine (for

example, low density polyethylene, low consistency polypropylene), vinyl chloride resin, an ethylene-vinyl acetate copolymer, a polyester (low consistency polyester) polycarbonate, ABS, silicone rubber (RTV rubber), thermoplastic polyurethane, etc. can be used. That whose melting point is about 120-200 degrees C as thermoplastics is suitable. What has the melting point higher than the glue line formation resin which is a fluororesin film, a polyolefine film, polyester, thermoplastic polyurethane, etc., and is used as a film can be used.

[0026] Formation of tubed covering in this case winds a film 14 around rodding, coats the external surface of a film 14 with a glue line, and arranges and heats the stent body 2 on it. It can carry out by rolling what produced that by which the film 14 was fixed to the inside of the stent body 2, then coated the inside of a film 15 with glue line 15a so that glue line 15a may become the inside on the external surface of the above-mentioned stent body 2, carrying out heating immobilization again, and carrying out extraction of the rodding. The stent body 2 may be beforehand coated with a glue line in that case. Although the whole stent body 2 is covered in the stent 1 of the above-mentioned example by the tubed covering 3, it is not limited to such a thing but you may have the tubed covering section 7 which is the part covered with the tubed covering 3, and the non-tubed covering section 8 which the stent body 2 exposes like the stent 80 shown in drawing 13 . That is, the side face of the central part of the stent body 2 is covered with the tubed covering 3, and, as for the stent 80 of this example, the both ends of the stent body 2 are not covered with the tubed covering 3. In the stent 80 in this case, in the tubed covering section 7, the free passage section (side attachment wall) of the stent body 2 is blocked, and prevents invasion of a body tissue from the exterior. Moreover, the non-tubed covering section 8 serves to make not easily temporary [to a living body lumen] in the stent 1, and it contributes to initial immobilization of the stent 80, and is fixed by an encapsulation being carried out to a body tissue in 2nd order. Moreover, it can change by the lesion section and, only for one end, the non-tubed covering section is [arrangement of tubed covering]. Moreover, it has the tubed covering section to both ends, and the non-tubed covering section may be arranged in the center section.

[0027] Furthermore, as shown in drawing 13 , when the stent 80 is equipped with the non-tubed covering section 8, in the front face which the stent body 2 exposes at least, it is desirable that a biocompatibility metal or biocompatibility resin is covered. As a biocompatible mater, the synthetic resin or the metal which has a biocompatible mater can be considered. As synthetic resin, although it can choose from the resin of a thermoplastic system or a heat-curing system, polyolefines (for example, polyethylene, polypropylene, ethylene propylene rubber, etc.), a polyvinyl chloride, an ethylene-vinylacetate copolymer, a polyamide elastomer, polyurethane, polyester, a fluororesin, silicone rubber, etc. can be used, and they are polyolefine, a polyamide elastomer, polyester or polyurethane, and biodegradation nature resin (for example, polylactic acid, polyglycolic acid, both copolymer) preferably, for example. the line from which a synthetic-resin coat constitutes the stent body 2 -- it is desirable that it is flexible to extent which does not become the hindrance of a curve of a spiral body. 5-300 micrometers of thickness of a synthetic-resin coat are 10-200 micrometers preferably.

[0028] As an approach of covering synthetic resin thinly on the front face of the stent body 2, there is chemical vacuum deposition covered while carrying out the polymerization of the approach and monomer which insert and cover the stent body 2 in the synthetic resin of a melting condition or a solution condition on the front face of the stent body 2, for example. When ultra-thin resin covering is required, covering which used the dilute solution, or chemical vacuum deposition is suitable. Furthermore, in order to raise a biocompatible mater more, an anti-thrombogenic material may be covered or fixed to the above-mentioned resin coat. independent [in various kinds of well-known resin] as an anti-thrombogenic material -- or although it can be mixed and used, the copolymer (for example, HEMA-St-HEMA block copolymer) of polyhydroxyethyl methacrylate, hydroxyethyl methacrylate, and styrene etc. can use it suitably, for example. As a biocompatibility metal, gold, silver, platinum, and titanium are mentioned, for example. The silicon carbide using the gold plate using the electroplating method as an approach of covering the front face of the stent body 2 with a metal, stainless steel plating using vacuum deposition, and a spatter, titanium nitride plating, gold plate, etc. can be considered.

[0029] Moreover, formation of the tubed covering 3 of the stent of this invention is not limited when using what serves as a film object beforehand. For example, the tubed covering 3 may be formed using the resin solution which has coat formation. the line of plurality [rodding / which specifically dissolved the polyurethane elastomer, the fluororesin elastomer, etc. in the proper solvent / the liquefied object and rodding] -- the filmy material (if it puts in another way basic layer) 23 which blocks the side attachment wall of the stent is formed by preparing what has arranged the spiral object and formed the gestalt of the stent body 2, being immersed, pulling up a stent body the whole rodding, in the above-mentioned liquefied object, and volatilizing a solvent. In addition, immersion of the stent body 2 to the above-mentioned liquefied object, raising, and the volatilization activity of a solvent may be done repeatedly. And after carrying out extraction of what equips with a filmy material (if it puts in another way basic layer) the external surface of the stent body formed by doing in this way from rodding, the tubed covering 3 is producible by forming a surface layer 24 by being immersed in the above-mentioned liquefied object, pulling up, and volatilizing a solvent again. In addition, although a thing the same as that of what was used first as a liquefied object immersed after rodding balking, or of the same kind is suitable, it is not limited to this. As long as there is an adhesive property with the formed filmy material (basic layer), what kind of thing may be used.

[0030] Moreover, although what equips both resin with an adhesive property is [that an adhesive property should just be what does not exfoliate when it changes into the condition of the tubed covering 3] suitable, you may paste up with a solvent. Thus, the formed tubed covering 3 serves as cross-section structure as shown in drawing 12 . In this case, the tubed covering 3 consists of a inner layer 23 which wraps the stent body 2 entirely, and an outer layer 24 which wraps a inner layer 23 entirely. As an example of a liquefied object, the THF (tetra-hydroxy furan) solution of a polyurethane elastomer, the DMF (dimethyl formaldehyde) solution of a fluororesin elastomer, etc. can be used. Moreover, the marker for localization can be stationed by applying and drying partial heating adhesion and a solvent to a marker at the edge, and adhesives, such as cyanoacrylate, may be used and arranged elsewhere. Moreover, also on the surface of a film, a marker may be stationed among films 14 and 15 and is good preferably to put between films and to arrange.

[0031] (Example 1) Cold working of the alloy pipe of a Ti Ni alloy (51 atom %nickel) was carried out, and the superelastic metallic pipe with the outer diameter of 9.9mm, the bore of 9.6mm, a thickness [of 0.15mm], and a die length of about 69mm was produced. Next, the stent body was produced in the YAG laser. the external surface of the stent -- chemical etching -- carrying out -- the line of a stent body -- the spiral body produced the stent body of a configuration as a cross-section configuration (cross section when cutting to the shaft orientations of a stent body) served as a rectangle which was able to take the angle mostly and shown in drawing 1 . After applying a fluororesin mold system elastomer solution to a porosity film, it heated for 5 minutes and 140 degrees C of fluororesin mold system elastomer covering porosity films were produced two sheets. Temporary immobilization was twisted and carried out so that a fluororesin mold system elastomer spreading side might become a rod an external surface side about the porosity film of one sheet.

[0032] The fluororesin elastomer solution was applied on the stent body, and after being air-dry, temporary immobilization of the stent body was carried out at the film by which temporary immobilization was carried out on the above-mentioned rod. And it twisted and temporary immobilization of the above-mentioned fluororesin mold system elastomer covering porosity film of the 2nd sheet was carried out on the outside so that a fluororesin system elastomer spreading side might become an inside side. And the rod heated at about 200 degrees C was pushed against the external surface of the stent formation object arranged as mentioned above, thermal melting arrival of the porosity film of two sheets was carried out, and formation and its fixing of tubed covering were performed. In addition, although the porosity film was carrying out opaque white for the existence of the usual pore, the rarefaction of it was carried out by pushing a heating rod. This is because the fluororesin elastomer which dissolved with heating invaded in pore. Thus, the stent of this invention of the gestalt shown in drawing 1 was produced. The whole stent body is covered in the stent of this example by tubed covering. This stent is

applicable to a constriction improvement of an iliac artery, a femoral artery, and a bile duct.
[0033] (Example 2) The stent body used the same thing as an example 1. 5% hydroxy [tetra-] furan solution of polyurethane was prepared. The tubed covering basic layer which repeats a stent body 10 times and becomes a stent body from polyurethane about the immersion and desiccation to a polyurethane solution in it was formed. It let the rod pass inside the stent body in which the tubed covering basic layer was formed, and again, immersion to a polyurethane solution and desiccation were performed 10 times, tubed covering was formed, and the stent of this invention was manufactured. Thus, the stent of this invention was produced. The whole stent body is covered in the stent of this example by tubed covering. This stent is applicable to a constriction improvement of an iliac artery, a femoral artery, and a bile duct.
[0034]
[Effect of the Invention] It is formed in the shape of a cylindrical shape with the body. the stent for detention of this invention in the living body -- a line -- It is the stent for detention in the living body which is compressed at the time of living body interpolation close, reduces the diameter of, and is restored to the configuration before contraction at the time of detention in the living body. This stent the line of a zigzag structure -- two or more lines spirally fabricated with the body -- a spiral object -- the shaft orientations of the stent -- almost -- parallel -- and each line -- with the stent body used as the gestalt arranged without a spiral object connecting this stent body -- said two or more lines -- while holding the arrangement condition of a spiral object, it has tubed covering which blockades the side face of said stent body. For this reason, it has sufficient flexibility, and there are few changing points as the whole stent, and the curve after detention is good.

[Translation done.]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1] Drawing 1 is the perspective view of one example of the stent of this invention.
[Drawing 2] Drawing 2 is the development view of the stent body of the stent shown in drawing 1.
[Drawing 3] the line by which drawing 3 is used for the stent of this invention -- it is an explanatory view for explaining the spiral configuration of a spiral body.
[Drawing 4] the line by which drawing 4 is used for the stent -- it is an explanatory view for explaining the spiral configuration of a spiral body.
[Drawing 5] Drawing 5 is the perspective view of other examples of the stent of this invention.
[Drawing 6] Drawing 6 is the development view of the stent body of the stent shown in drawing 5.
[Drawing 7] Drawing 7 is the perspective view of other examples of the stent of this invention.
[Drawing 8] Drawing 8 is the development view of the stent body of the stent shown in drawing 7.
[Drawing 9] Drawing 9 is the perspective view of other examples of the stent of this invention.
[Drawing 10] Drawing 10 is the development view of the stent body of the stent shown in drawing 9.
[Drawing 11] Drawing 11 is an explanatory view for explaining the cross-section structure of one example of the stent of this invention.
[Drawing 12] Drawing 11 is an explanatory view for explaining the cross-section structure of other examples of the stent of this invention.
[Drawing 13] Drawing 13 is the perspective view of other examples of the stent of this invention.

[Description of Notations]
1 Stent for Detention in the Living Body
2 Stent Body
21, 22, 23, and 24 a line -- spiral object
3 Tubed Covering

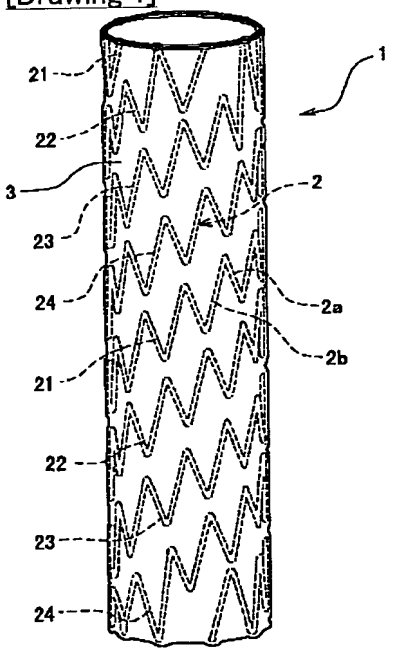
[Translation done.]

* NOTICES *

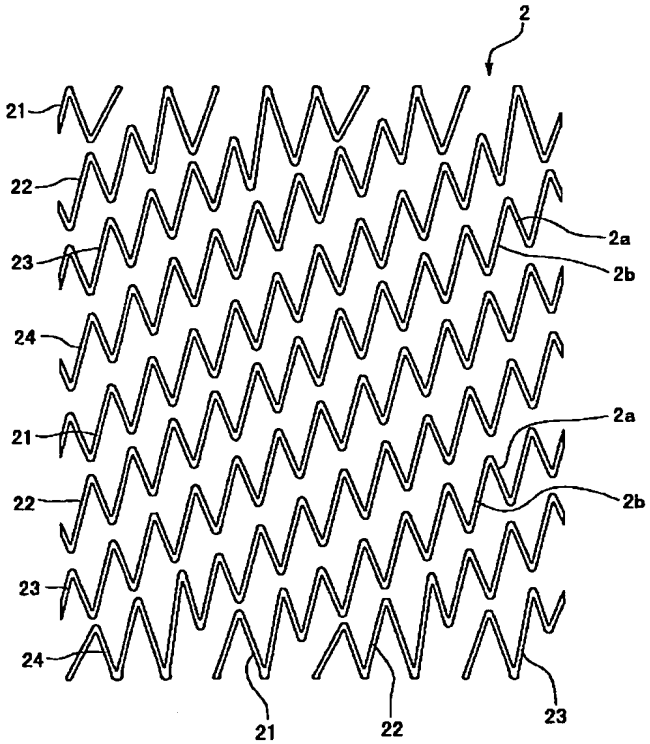
1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DRAWINGS

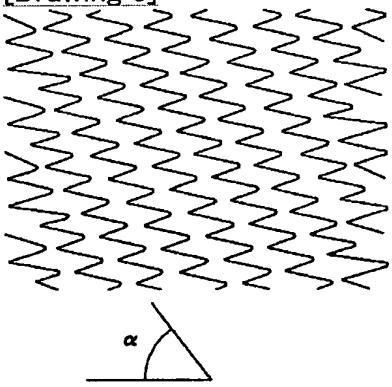
[Drawing 1]



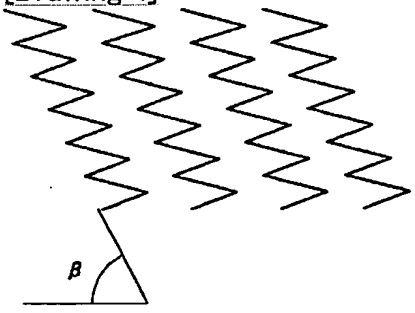
[Drawing 2]



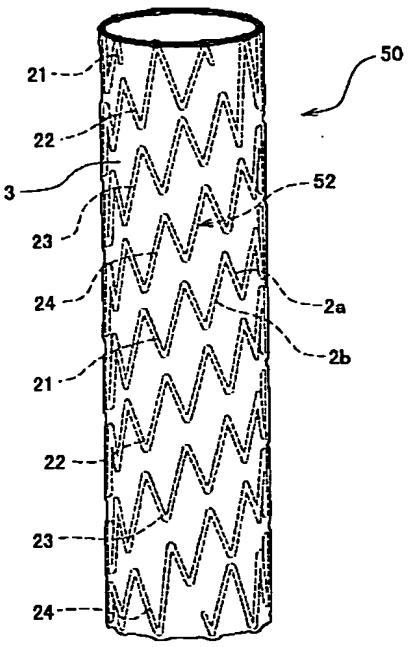
[Drawing 3]



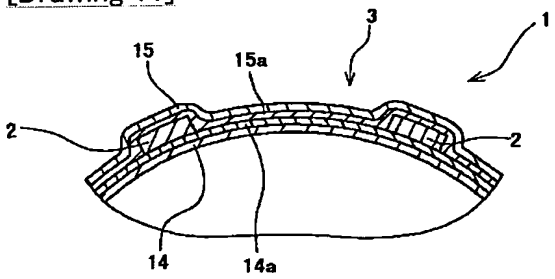
[Drawing 4]



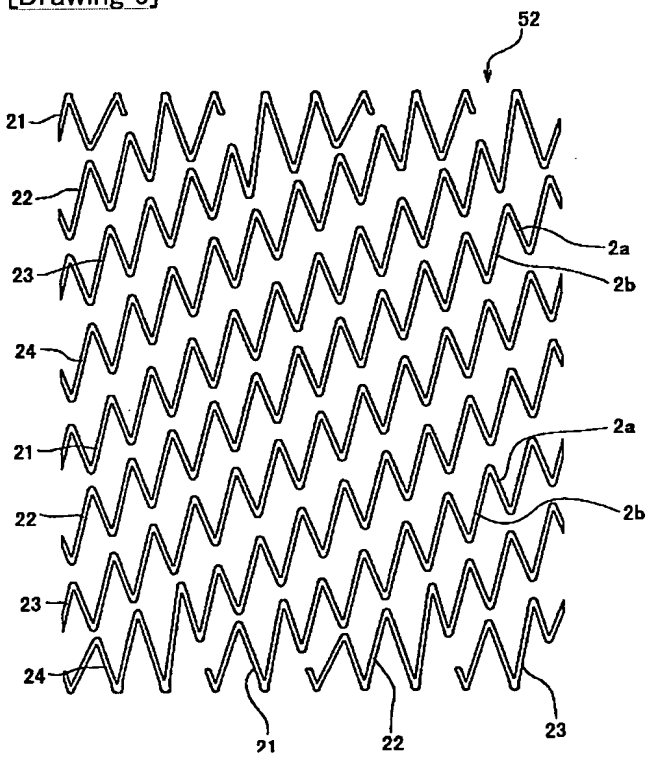
[Drawing 5]



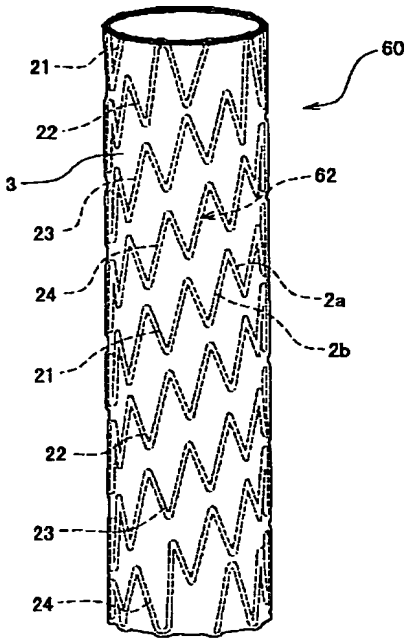
[Drawing 11]



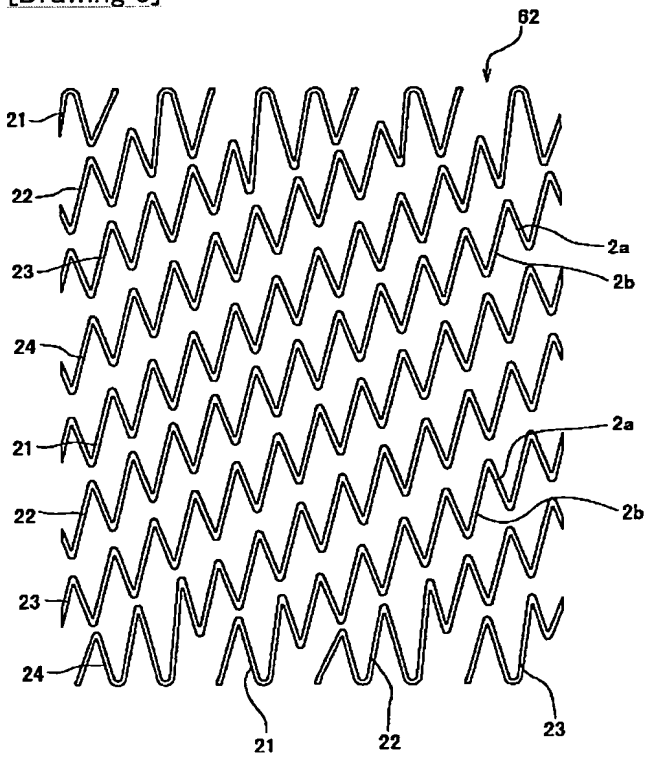
[Drawing 6]



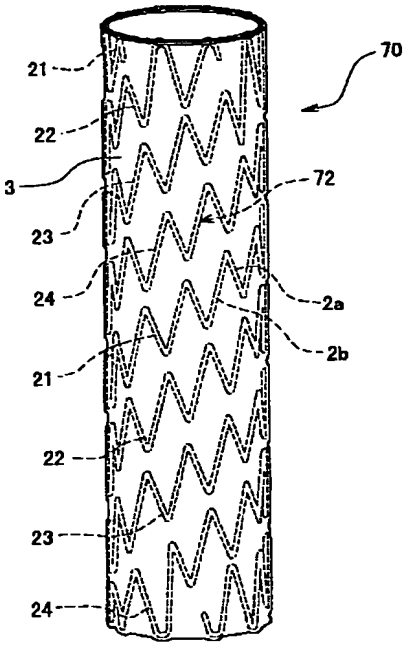
[Drawing 7]



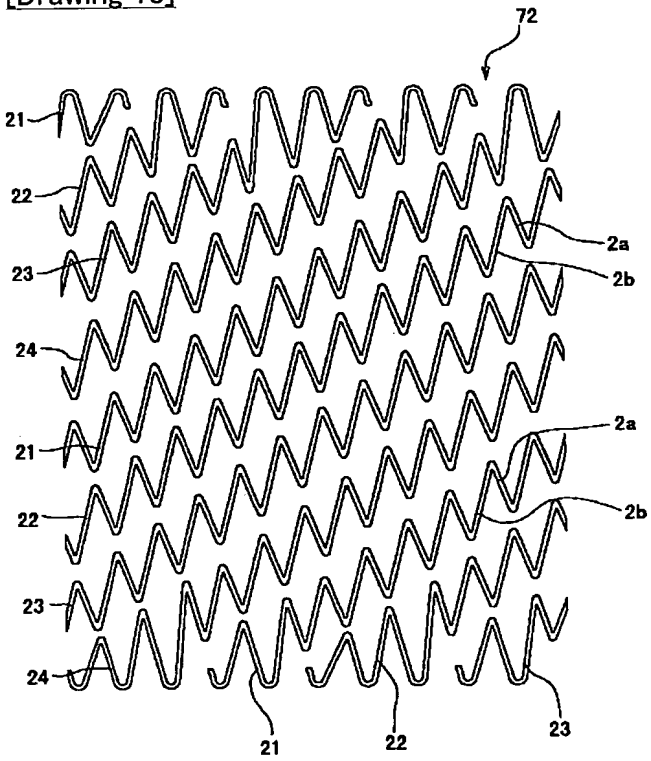
[Drawing 8]



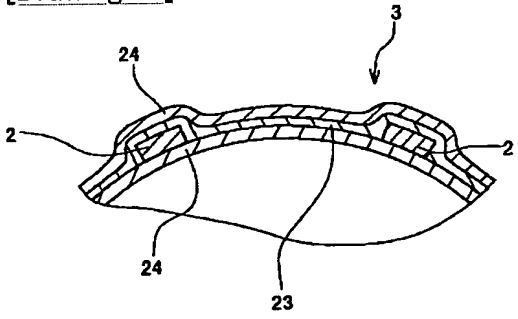
[Drawing 9]



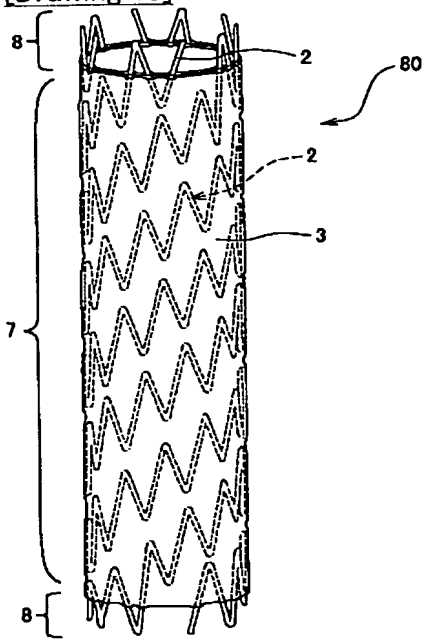
[Drawing 10]



[Drawing 12]



[Drawing 13]



[Translation done.]